HYGIA
HEALTH SERVICES

APR 12 2002

K012650

510(k) Summary

Summary

Substantial Equivalence Summary for the Hygia Health Services Reprocessed NuTech® Foot Wrap.

In accordance with 21 CFR Part 807.92, this summary is submitted by:

Hygia Health Services, Inc.
2800 Milan Court
Suite 259
Birmingham, Alabama 35211

Date: August 6, 2001

1. Contact Person

Geoff M. Fatzinger
Director, Compliance and Regulatory Affairs
(205) 943-6670

2. Name of Device

Classification Name: Compressible Limb Sleeve
Common or Usual Name: Intermittent Pneumatic Compressible Limb Sleeve
Review Panel: Cardiovascular
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed NuTech® Foot Wrap.

3. Predicate Device

Classification Name:	Compressible Limb Sleeve
Common Name:	Intermittent Pneumatic Compressible Limb Sleeve
Classification:	Class II
Proprietary Name:	NuTech® PlexiPulse Foot Wrap Garment

4. Statement of Substantial Equivalence

The Hygia Health Services Reprocessed NuTech® Foot Wrap employs no new technology other than the method used to reprocess the garment in order to allow the device to be utilized more than once. The Hygia Health Services Reprocessed NuTech® Foot Wrap is substantially equivalent to the NuTech® PlexiPulse Foot Wrap in that the basis of operation for both of the devices is the intermittent inflation of a single bladder, which is placed around the patient's plantar arch. The garments are then connected to a controller. Inflation of the device is accomplished using ambient air, and a controller cycle that functions to alternately inflate and deflate the sleeves in a predetermined manner and interval.

The Hygia Health Services Reprocessed NuTech® Foot Wrap is substantially equivalent in function, operating parameters, and intended use to the NuTech® PlexiPulse Foot Wrap that is currently commercially available and in distribution. The predicate device, the NuTech® PlexiPulse Foot Wrap, is marked for "single-patient use only". Hygia Health Services does not change the device in any way except to render the device "reusable" by placing it through a scientifically validated thermal kill pasteurization process. The Hygia Health Services HLD protocol does not alter the device's efficacy, safety, composition, or intended use.

5. Description of the Device

The Hygia Health Services Reprocessed NuTech® Foot Wrap Garment is a compressible limb device that is placed around the patient's foot and when attached to an approved controller, provides intermittent pneumatic compression. The garment is constructed out of brushed nylon with polyester foam backing. The single bladder is constructed out of poly vinyl chloride (PVC), which is RF welded at the seams. The inflation/deflation tube is also composed of PVC. The hook fasteners are made of polyethylene. The tube terminates in a snap lock connector. The garments are placed around the foot at the area of the plantar arch and secured with a hook and loop fastener. As the garment compresses the plantar plexus, veins collapse longitudinally, increasing the venous pressure thus ejecting the blood upward. After compression, the devices deflate allowing the veins to refill and bring oxygenated blood to the lower limbs. The controller predetermines the inflation and deflation sequence. The pressure of compression is determined by the controller and is adjusted by altering the readout on the controller.

6. Intended Use of Device

The Hygia Health Services Reprocessed NuTech® Foot Wrap operates in the identical manner as the predicate device, the NuTech® PlexiPulse Foot Wrap Garment. It is designed to apply compression to a patient's plantar plexus for the prevention of deep vein thrombosis (DVT) as well as the treatment of edema secondary to venous insufficiency. The device may be used in both the home and institutional settings on patient populations for which a leg or calf compression device would not be applicable.

7. Technological Characteristics

The technological characteristics of the Hygia Health Services Reprocessed NuTech® Foot Wrap are identical to the original NuTech® PlexiPulse Foot Wrap Garment in overall design, materials, energy source, mode of operation, and performance characteristics.

8. Performance Data

Nonclinical Tests- Comparative bench testing was utilized to assess and prove similarity of function between the Hygia Health Services Reprocessed NuTech® Foot Wrap and the predicate device, the NuTech® PlexiPulse Foot Wrap Garment. All tests found that functional and operational performance characteristics including compression, pressure control, timing sequence, and both safety and operational parameters used when connected to a controller were substantially equivalent.

9. Clinical Data

Clinical tests were summarized in support of this pre-market notification submission.

Test Conclusions- Nonclinical and clinical test results of the Hygia Health Services Reprocessed NuTech® Foot Wrap indicated substantial equivalence in all aspects to the predicate device, the NuTech® PlexiPulse Foot Wrap Garment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Mr. Geoff M. Fatzinger, BS MS
Director, Compliance and Regulatory Affairs
c/o Hygia Health Services, Inc.
2800 Milan Court, Suite 259
Birmingham, AL 35211

Re: K012650
Trade Name: Hygia Health Services Reprocessed NuTech® Foot Wrap
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 7, 2002
Received: February 8, 2002

Dear Mr. Fatzinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

P1/2

Indications For Use

Applicant: Hygia Health Services, Inc.

510(k) Number: K012650

Device Name: Hygia Health Services Reprocessed NuTech® Foot Wrap

Indications For Use:

The Hygia Health Services Reprocessed NuTech® Foot Wrap is designed to enhance circulation of blood in the venules and arterioles. It to be used by patient's in both the home and institutional settings as a non-invasive therapeutic method to prevent:

- Deep vein thrombosis
- Reduce wound healing time
- Treat and assist healing of venous leg ulcers
- Reduce edema caused by venous insufficiency in the lower extremities
- Decrease compartmental pressures

PRECAUTIONS AND CONTRAINDICATIONS

Contraindications:

Wraps may not be recommended for patients with the following:

1. Congestive heart failure
2. Known or suspected deep vein thrombosis
3. Severe arteriosclerosis or other ischemic vascular disease
4. Any local leg condition in which the wrap would interfere such as dermatitis, gangrene, recent skin graft, or untreated infected wounds

Precautions:

1. One must ensure that the wrap is applied properly.

2. One must ensure that the wrap is correctly connected to the pump and that the connection is secure.

3. If numbness, tingling, or leg pain is experienced by the patient, the wrap should be removed.

Division of Cardiovascular & Respiratory Devices
510(k) Number K012650

Prescription Use X
(Per 21 CFR 801.109)